James R. Overman, N.D.
Owner
Precision Herbs, LLC.
9804 Township Road 89
Killbuck, OH. 44637

December 7, 2011

Department of Health & Human Services
Food and Drug Administration
Mr. Steven D. Silverman – Director
Office of Compliance
10903 New Hampshire Avenue
Silver Spring, MD 20993

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED

H. Charles Cathlin Jr.
Food and Drug Administration
10903 New Hampshire Avenue, WO66-2648
Silver Spring, MD 20993

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED

Re: Response to Warning Letter Case # 229574; dated December 1, 2011

Dear Mr. Silverman and Mr. Cathlin Jr.;

The FDA was notified in October of 2009 (See Exhibit "A") that the company Precision Herbs, LLC., has ceased marketing the products that you described in your letter dated December 1, 2011.

Furthermore, the Private Healthcare Membership Association web site www.precisionherbs.com is a private membership association website of Precision Herbs, a Private HealthCare Membership Association.

The formation and involvement of private membership associations are exempt under Title 21 U.S.C. § 301 et. seq. because the U.S. Supreme Court has ruled that the FDA has the authority under Title 21 U.S.C. to promulgate regulations to protect the public health. (Emphasis added.) Young v. Community Nutrition Institute, et al., 476 U.S. 974. Throughout Title 21 U.S.C. 301 et. seq. and the FDA regulations, there are numerous references to the statutes and regulations being necessary for the protection of public health. See 21 U.S.C. 346.

No where in FDA statutes or regulations does the FDA jurisdiction or authority extend to the protection of private association member's health as a general rule. Granted that if a private membership association has activities that rise to a level of a clear and present danger of substantive evil, the FDA can investigate and prosecute. The marketing and use of our products mentioned in your letter could never rise to that level.

In addition, the U.S. Supreme Court has ruled that the public domain is separate from the private domain of a private membership association in numerous cases. N.A.A.C.P. v. Button, 371 U.S. 415; Pierce v. Society of Sisters, 268 U.S. 510; Roberts v. United States, 82 L.Ed. 2d 462; Baird v. Arizona, 401 U.S. 1. These cases also have ruled that private membership associations are outside your jurisdiction and authority being exempt.

If your letter is concerning our Private Membership Association then this letter is our official notice that your FDA Warning Letter concerning our private membership association is erroneous, illegal and bogus.

Your agency has no jurisdiction, authority or legal standing to issue an FDA Warning Letter concerning the private membership association on several grounds.

1.) The FDA's jurisdiction and authority is limited to situations which present an imminent hazard to the public health. American Public Health Ass'n. v. Veneman, 342 F.Supp. 105.

2.) Referring to a Federal Statutory Rule of Interpretation or Construction, it states, "An agency's actions are limited to whatever the statutes and/or regulations permit." No where in FDA statutes or regulations does it permit or authorize the FDA to issue "Warning Letters" as part of their administrative procedures concerning investigations or procedures. Therefore, your Warning Letter concerning our private association is bogus, illegal and should not have been issued.

3.) FDA Warning Letters were never intended to be final demands, but intermediate requests for voluntary compliance. Holistic Candlers and Consumer Association v. F.D.A., 2011 WL 923357. But, no where in your FDA Warning Letter does the agency give notice or a disclaimer that the FDA Warning Letter was never intended to be a final demand, but an intermediate request for voluntary compliance. This is error of omission that is misleading and makes your Warning Letter a bogus and fraudulent document. Our association has voluntarily complied with numerous U.S. Supreme Court decisions which are the Supreme Law of the Land.

4.) In addition, no where in the FDA Warning Letter does it mention any legal action against manufacturers or the fact that the FDA has not initiated enforcement action against any manufacturer, or that the letter is informal, advisory, and not intended to serve as a final agency action. Holistic Candlers and Consumer Association v. F.D.A., supra. Again, this is misrepresentation and fraudulent error by omission causing inferences and allegations that are damaging to the integrity, well-being and future success of our private association.

The fact is that your FDA Warning Letter is not authorized or permitted by your agency, and it is incorrect, fraudulent and void. Therefore, it is demanded that the FDA Warning Letter

concerning our association be rescinded, cancelled, abated and voided. This includes any and all use of the FDA Warning Letter which must be removed from any communication resource or website.

Please notify me within 15 days of your action.

Sincerely,

Precision Herbs, LLC

Precision Herbs
A Private Membership Association

by James R Overman
James R. Overman N.D., Trustee

Attachment: FDA Warning Letter dated 12/1/2011

Exhibit: A

EXHIBIT "A"

James R. Overman
Precision Herbs L.L.C.
9804 TR 89
Killbuck, OH. 44637
330-276-6511

October 1st, 2009

U. S. Food and Drug Administration
Karen Gale Sego
Compliance Officer
6751 Steger Dr.
Cincinnati, OH. 45237-3097

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

U. S. Food and Drug Administration
Cincinnati District
Annemarie Kleiza
Investigator
3820 Center Road
Brunswick, OH. 44212

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

U. S. Food and Drug Administration
Cincinnati District
Steve Kilker
Investigator
3820 Center Road
Brunswick, OH. 44212

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

U. S. Food and Drug Administration
Cincinnati District
Benjamin J. Dastoli
Investigator
3820 Center Road
Brunswick, OH. 44212

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

U. S. Food and Drug Administration
6751 Steger Dr.
Cincinnati, OH. 45237-3097

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Re: Rescission of Activities and Practices Involving Herbs, Electric Devices and Subtle Energy Devices.

Dear Sir:

This letter is written to inform your agency that any and all manufacturing and sale of our products to the public is hereby terminated. We now understand that your agency has a mandate from Congress to protect the public. We also understand and respect that principle and we will assume that a cease and desist order had been issued by your agency without any further action on your part.

Be it known that we will fully comply with FDA statutes, regulations and orders in the future. We are also aware that your jurisdiction and authority is limited to the public domain, except for clear and present dangers of substantive evil per U.S. Supreme court decisions.

We also apologize for the expense, time and effort your agency has expended thus far and hope you realize that we never had any intent to violate the law in the past or future. We acted upon information and understandings of our research and various other persons and organizations. Apparently, some of that research and information was incorrect which has caused some concern and an investigation on your part. Please inform us as to anything we can do to redeem and mitigate ourselves from any civil and or/criminal sanctions by your agency. We believe that our only fault is a good faith mistaken understanding of the law.

Sincerely,

_____
James R. Overman

Precision Herbs L.L.C.,

By_____
James R. Overman, Chairman